DEPARTMENT OF HEALTH & HUMAN SERVICES

95009d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 30, 2004 W/L: 49-04

Mr. James May, President
United American Industries
2546 W. Birchwood Avenue, Suite 104
Mesa, AZ 85202

Dear Mr. May:

From September 24 through October 1, 2003, the Food and Drug Administration (FDA) conducted an inspection of your firm located at 2546 W. Birchwood Avenue, Suite 104, Mesa, Arizona. The inspection was conducted to determine your firm's compliance with the Federal Food, Drug, and Cosmetic (the Act) and the applicable regulations in Title 21, Code of Federal Regulations (CFR). You may find copies of the Act and these regulations through links in FDA's home page at www.fda.gov.

On July 28, 2004, FDA collected labels for several of your products, including "Wisdom Herbs Sweet Leaf -Stevia Extract," "Wisdom Herbs-Stevia Herbal Tea," and "Wisdom Herbs-Stevia Concentrate." Our review of your labels found that your products are represented for use in conventional foods within the meaning of § 201(ff)(2)(B) of the Act (21 U.S.C. 321(ff)(2)(B)).

Examples of label statements that establish that your stevia products are represented for used as conventional foods include:

- Wisdom Herbs Sweet Leaf-Stevia Extract: "Suggested Use: Add 1/3 teaspoon to supplement 2 quarts of unsweetened beverage, or use sparingly to supplement desired food preparations. Reduce sugar usage by one cup for each 1/3 teaspoon of Stevia Extract used."
- Wisdom Herbs-Stevia Herbal Tea: "Add Stevia to other teas and you may find you do not have to use sugar or artificial sweeteners to achieve the desired taste." "A refreshing, naturally sweet way to Enhance Other Teas..."

- Wisdom Herbs-Stevia Concentrate: "Use direct from dropper or add 3-6 drops to beverages and food according to need and taste."

FDA has reviewed the regulatory status of the ingredients declared on the label of these beverage products. These products are adulterated under section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C)) in that they bear or contain an unsafe food additive, stevia (*Stevia rebaudiana)* or stevia extract. The regulations pertaining to food additives are in 21 CFR Part 170.

Any substance intentionally added to a conventional food, such as a beverage product, must be used in accordance with a food additive regulation approving the substance for that use, unless the substance is generally recognized as safe (GRAS) among experts qualified by scientific training and experience to evaluate its safety ("qualified experts") under the conditions of its intended use, or is otherwise exempt from the food additive definition in section 201(s) of the Act (21 U.S.C. 321(s)).

FDA's regulations in 21 CFR Part 170 describe criteria for eligibility for classification of a food ingredient as GRAS. Under 21 CFR 170.30(a), general recognition of safety must be based only on the views of qualified experts. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

FDA's regulations in 21 CFR Part 170 define "common use in food" and establish criteria for eligibility for classification as GRAS through experience based on common use in food. Under 21 CFR 170.3(f), "[c]ommon use in food means a substantial history of consumption of a substance for food use by a significant number of consumers." Under 21 CFR 170.30(c)(1), "[g]eneral recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information." Importantly, however, the fact that a substance was added to food before 1958 does not, in itself, demonstrate that such use is safe, unless the pre-1958 use is sufficient to demonstrate to qualified experts that the substance is safe when added to food.

Similarly, FDA's regulations in 21 CFR Part 170 define "scientific procedures" and establish criteria for eligibility for classification as GRAS through scientific procedures. Under 21 CFR 170.3(h), "[s]cientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance." Under 21 CFR 170.30(b), "[g]eneral recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient." Section 170.30(b) further states that general recognition of safety through scientific procedures is ordinarily based upon published studies, which may be corroborated by unpublished studies and other data and information.

FDA's regulations in 21 CFR Part 170 define "safe" and "safety." Under 21 CFR 170.3(i), "Safe or safety means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." The regulation provides that, in determining safety, the following factors are to be considered: (1) The probable consumption of the substance and of any substance formed in or on food because of its use; (2) the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet; and (3) safety factors which, in the opinion of qualified experts, are generally recognized as appropriate. Such safety factors ordinarily are established through extensive testing in animals to determine whether consumption of the ingredient produces adverse effects when consumed chronically (i.e., on a daily basis over the course of a lifetime (Ref. 1)).

In assessing the GRAS status of stevia for use in beverage products, such as those that you manufacture, we considered the criteria described above. For example, while FDA has received inquiries and petitions for the use of stevia or stevia extracts in food, data and information necessary to support the safe use have been lacking. In fact, literature reports have raised safety concerns about the use of stevia, including concerns about control of blood sugar, and effects on the reproductive, cardiovascular and renal systems.

In light of these safety concerns, the use of stevia in the beverage products identified above do not satisfy the criteria for GRAS status outlined above. Further, FDA is not aware of any other exemption from the food additive definition that would apply to stevia for use as an ingredient in beverages. Therefore, stevia used in this manner is a food additive under section 201(s) of the Act and is subject to the provisions of section 409 of the Act (21 U.S.C. 348). Under section 409, a food additive is required to be approved by FDA for its intended use prior to marketing. Stevia (*Stevia rebaudiana*) *is* not an approved food additive for use in beverages. Therefore, the products "Wisdom Herbs Sweet Leaf-Stevia Extract," "Wisdom Herbs-Stevia Herbal Tea," and "Wisdom Herbs-Stevia Concentrate" as beverages containing stevia, are adulterated within the meaning of section 402(a)(2)(C) of the Act.

You should take prompt action to correct these violations and prevent its future recurrence. It is the responsibility of a manufacturer to ensure that foods the firm markets are safe and otherwise in compliance with all applicable statutory and regulatory requirements. This is not intended to be an all-inclusive review of the labeling and products that your firm markets. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products. Failure to do so may result in enforcement action without further notice.

Please advise this office in writing within fifteen (15) days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and the date by which each such item will be corrected and documented.

Please send your reply to the Food and Drug Administration, Attention: Acting Director, Compliance Branch, 19701 Fairchild, Irvine, CA 92612-2445. This case has been assigned to Compliance Officer MaryLynn Datoc. If you have any questions regarding any issue in this letter, you may contact Ms. Datoc at telephone number (949) 608-4428 if you have any questions.

Sincerely,

Alonza E. Cruse
Director, Los Angeles District

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-357
Sacramento, CA 94234-7320

1. *Toxicological Testing of Food Additives*, available at http://vm.cfsan.fda.gov/~dms/opatg1.